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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------------|
| 10/531,346 | 04/15/2005 | Stefan Frahling | GIL-16027 | 8225 |
| 7609 7590 02/25/2008 RANKIN, HILL & CLARK LLP 925 EUCLID AVENUE, SUITE 700 CLEVELAND, OH 44115-1405 | | | EXAMINER PALENIK, JEFFREY T | |
| | | | ART UNIT 1615 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/531,346 | Applicant(s) FRAHLING ET AL. | |
| | Examiner Jeffrey T. Palenik | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>19 August 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Remarks

Applicant's election without traverse of Group I, claims 1-6, 9 and 10, in the reply filed on 11 January 2008 is acknowledged.

It is further acknowledged that Applicant has elected to withdraw Group II, claims 12-21.

Claims 12-21 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 16 November 2007.

The remaining claims 1-11 are presented and represent all claims under consideration.

Priority

This application is the National Stage filing of International Patent Application No. PCT/EP03/10853, filed 30 September 2003, and German Applications 10248314.0, filed 16 October 2002, and 10317982.8, filed 17 April 2003. Examiner finds that Applicant's filing meets the priority requirements for the International Application, but not the Foreign Application.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Acknowledgment is made within the Application Data Sheet of Applicants' claim

for priority under 35 U.S.C. 119(a)-(d) based upon applications filed with the European Patent Office on 16 October 2002, and 17 April 2003. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said applications, since the United States application was filed more than twelve months thereafter.

As such it is determined that the earliest effective U.S. filing date to be 30 September 2003.

Information Disclosure Statement

An Information Disclosure Statement filed 19 August 2005, is acknowledged and has been reviewed.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claims 2, 3, and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 2 and 3 recite the limitations “for a cosmetic purpose” and “for a therapeutic purpose”, respectively. Per MPEP 2111.02 (II), the “purposes” do not add

anything further to the method of claim 1. Therefore, both claims are read as applying the formulation resulting from the method of claim 1.

Claim 10 merely recites the same limitations as claim 1, but uses broader limitations and condenses the three steps into one.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble in the independent claim 1 recites "A method comprising." The claim further recites limitations for preparing a composition as well as using said composition. It is unclear what type of method is being claimed. Herein, for the purposes of examination on the merits, the Examiner interprets the elected method to be directed towards a "method of using comprising..."

Claim 1 recites a method comprising "optionally one or more active substances" and "optionally one or more auxiliary substances". Subsequent to the use of the term "optionally" in reference to the active and auxiliary substances, the recitation "and/or" is stated in the "contacting" step of claim 1. The recitation "and/or" is also stated in the "applying" step of claim 1. It is not clear whether the "optional" limitations are a part of

the invention, since, in its broadest reasonable interpretation, the claim may include or exclude one or both of the ingredients in addition to having a wide array of applicability.

The metes and bounds of the composition prepared in claim 1 are not clear. The first step of the method recites providing a scaffold-based, shaped article (i.e. a solid formed article). The following step recites the preparation of a solution or gel. The ultimate compositional phase of the article created in claim 1 is not clear.

The dependent claims 2-6 are rejected since they depend directly from claim 1.

Similar to claim 1, dependent claims 9 and 10 recite "and/or" within their respective limitations. It is not clear which limitations are part of the invention.

Claim 9 is further deemed vague and indefinite because of the recitation "wherein the shaped article is applied..." Since the claim is reciting only "the shaped article", it is not expressly clear in what form said article is being used (i.e. pre- or post-wetting step).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Dogliani (EP 0 888 769).

The instant claims, as discussed above, are read as being directed towards a method of using an applicable composition. Given its broadest reasonable interpretation,

the independent claim 1 is directed towards using a formed composition comprising a shaped article that is contacted with an aqueous solution and applied to the skin or hair of a mammal. Claim 4 further limits the scaffold-forming agent of claim 1 to at least one polysaccharide or a derivative thereof. Claim 5 further limits the scaffold-forming agent of claim 1 to sodium alginate. Claim 9 further limits the use of the composition of claim 1 such that the user applies the composition to their own skin or hair. Claims 2, 3, and 10 each recite limitations, as described above.

Such application methods are taught by Dogliani. Thick, rigid sheets which are able to be rehydrated and able to be directly applied to the skin of the face or body are taught (col. 1, lines 3-17). Sodium alginate is taught (col. 1, lines 43-46). Applicants provide a limited definition for the term "polysaccharides". However, it does include sodium alginate as an especially preferred example (pg. 6, lines 22-24). Active agents included in the composition are taught (col. 1, lines 40-42) as are auxiliary substances (col. 1, lines 47-52).

Claims 1-3, 6, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Wunderlich et al. (U.S. Patent 5,578,307).

The instant claims, as discussed above, given their broadest reasonable interpretation, are able to be read as being directed towards a either a method of using an applicable composition or a method of preparing a useable composition (claim 1). Claim 6 limits the shape of the article of claim 1 to a sphere ranging in volume from 0.1 mL to 6

mL, wherein 1 cm³ equals 1 mL. Claim 9, as stated above, limits the range of the range of application.

Such preparation methods are taught by Wunderlich et al. Claims 16, 17, 22 and 28 teach a process for the preparation of shaped articles which are mixable with aqueous plant extracts to produce a dispersion of a scaffolding-agent (e.g. skeleton builder). Claim 17 limits the form of the skeleton builder to a "sol/gel", which is interpreted to mean a soluble gel, since Wunderlich teaches it as being thermoreversible (claim 2). Claim 22 teaches that resulting pellets are formulated with a cream or hydrogel base. The pellets are further taught as being spherical in shape and having diameter of up to 12 mm (col. 4, lines 31-34). A diameter of 12 mm, equates to a spherical particle of approximately 0.9 mL.

Therefore each of the aforementioned limitations is taught by the references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dogliani (EP 0 888 769) in view of Wunderlich et al. (U.S. Patent 5,578,769).

The instant claims, as discussed above, given their broadest reasonable interpretation, are able to be read as being directed towards a either a method of using an applicable composition or a method of preparing a useable composition (claim 1). The remaining dependent claims 2-6, 9 and 10, individually further limit the chosen method, as described above. Claim 4 further limits the method such that the scaffold-forming agent is at least one polysaccharide or a derivative thereof.

Dogliani teaches a method comprising the provision of a sodium alginate-based, shaped article which is wettable and applicable to human skin, as described above. However, he does not teach that the shaped article of the composition is a sphere having the claimed volume range.

Wunderlich et al. teaches a method comprising mixing sphere-shaped pellets with aqueous plant extracts (i.e. wetting the sphere-shaped particles) to form a hydrogel formulation applicable to human skin (claim 16, 22 and col. 16, lines 15-18). Spherical pellets within the claimed range are also taught (col. 4, claims 31-34).

In view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to substitute a shaped article comprising wettable, sphere-shaped particles for thick, rigid, wettable sheets with a reasonable expectation of forming

a hydrogel capable of being applied to the skin or hair of a human or animal. Such would have been obvious in the absence of evidence to the contrary because given the breadth of the instant claims allows, both the application method of Dogliani and the preparation method of Wunderlich read on said instant claims, as described above.

As to the claimed volume range of the sphere of the instant claim 6, neither of the references teaches the exact range limitations claimed by Applicants. The volume of the sphere(s) comprising the shaped article of the instant method is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal volume in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amounts would have been obvious at the time of Applicant's invention.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

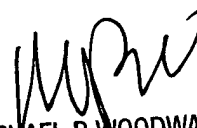
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey T. Palenik
Patent Examiner


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